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| 10/568,108      | 02/13/2006  | Alexandre Avrameas   | 62745.000020        | 5477             |

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| EXAMINER |
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HA, JULIE

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| ART UNIT | PAPER NUMBER |
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1654

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07/23/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/568,108

Applicant(s)

AVRAMEAS, ALEXANDRE

Examiner

Julie Ha

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 6, 13-18 and 21-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12, 19, 20 and 28 is/are rejected.
- 7) ☒ Claim(s) 8-12, 19-20 and 28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Response to Election/Restriction filed on June 18, 2007 is acknowledged. Claims 1-28 are pending in this application.

#### ***Restriction***

1. Applicant's election of Group II (claims 3 and 8) drawn to an amino acid sequence  $(X_1)_p$ XBBBXBXXBXXBXXB and SEQ ID NO:2 in the reply filed on June 18, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 21-27 are withdrawn from further consideration, pursuant to 37 CFR 1.142(b), as being drawn to nonelected invention, there being no allowable generic or linking claim. Claims 6 and 13-18 are withdrawn from further consideration as being drawn to nonelected species. A search was conducted on the elected species of SEQ ID NO:2. This appears to be free of the prior art. The search was extended to SEQ ID NO:1, and this too appears to be free of the prior art. The search was further extended to the broad Markush claim 1, and prior art was found. Claims 1-5, 7-12, 19-20 and 28 are examined on the merits in this office action.

***Objection-Minor Informalities***

2. The title is objected to because the title is too long. The title is limited to 2-7 words maximum. A new title is required that is clearly indicative of the invention to which the claims are directed.
3. Claims 8-12, 19-20 and 28 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 8. See MPEP § 608.01(n).
4. Claim 20 is objected to because of the following informalities: Claim 20 recites the language "the use of". "Use" claim language is improper under U.S. practice. Appropriate correction is required.

***Objection-Claims***

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte*

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*Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation X is a no-basic, and the claim also recites preferably hydrophobic amino acid which is the narrower statement of the range/limitation.

***Rejection-35 U.S.C. 112, 1<sup>st</sup>***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-5, 7, 9-12, 19 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

8. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties,

number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

11. In the instant case, the claims are drawn to an amino acid sequence having the following formula:  $(X_1)_p[(X)_o(B)_nXBXXB]_m(X_2)_q$  wherein  $X_1$  and  $X_2$  are amino acid sequences of 1 to 20 amino acids,  $p$  and  $q$  are whole numbers between 0 and 5,  $B$  is a basic amino acid,  $X$  is a non-basic amino acid,  $n$  is 2 or 3,  $m$  is 1 to 4 and  $o$  is 0 or 1.

The generic statement an amino acid sequence having the formula

$(X_1)_p[(X)_o(B)_nXBXXB]_m(X_2)_q$  does not provide ample written description for the compounds since the claims do not describe a single structural feature. The specification does not clearly define or provide examples of what qualify as compounds of the claimed invention.

12. As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is broad generics with respect all possible compounds encompassed by the claims. The possible structural variations are limitless to any class of peptide or a peptide-like molecule that can form peptide bonds. It must not be forgotten that the MPEP states that if a peptide is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the claims may recite some functional characteristics, the claims lack written

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description because there is no disclosure of a correlation between function and structure of the compounds beyond compounds disclosed in the examples in the specification. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of derivatives. The specification is void of organic molecules that functions as a peptide-like molecule that qualify for the functional characteristics claimed as a peptide or a peptide-like molecule or other peptidic molecules, and other synthetic peptide or peptide-like molecule that can form peptide bonds.

13. The specification is limited to the peptide or peptide-like molecules that have the same function: being able to facilitate penetration of a substance of interest inside cells and/or cell nuclei. The working example describes SEQ ID NOS: 1-20 (see pp. 23-27). The specification also describes SEQ ID NOS: 4, 5, 6, 8, 9, 3 and 7 with C-terminal Cystein (see p. 22, paragraphs [0626] and [0627]). The specification does not describe any other amino acid sequence comprising the formula  $(X_1)_p[(X)_o(B)_nXBXXB]_m(X_2)_q$ , wherein X1 and X2 are amino acid sequences of 1 to 20 amino acids, p and q are whole numbers between 0 and 5, B is a basic amino acid, X is a non-basic amino acid, n is 2 or 3, m is 1 to 4 and o is 0 or 1. Descriptions of SEQ ID NOS: 1-20 and 3-9 with C-terminal Cystein are not sufficient to encompass numerous other amino acid sequences that belong to the same genus. For example, there are varying lengths, varying amino acid compositions, and numerous distinct qualities that make up the genus. For example, since X1 and X2 are amino acid sequence of 1 to 20 amino acids, and p and q are whole numbers between 0 and 5, there can be at least 20 X 5 amino acids for X1

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sequence and 20 X 5 for X2 sequence. The 20 amino acids can be any amino acids (including natural, non-natural, and peptide mimetics), since there is no limitations set forth. Furthermore, X is a non-basic amino acid, which means that it can be any of the 17 amino acids (A, I, L, M, F, W, V, Y, G, S, T, C, P, N, Q D or E). B is a basic amino acid (H, K or R) and n is 2 or 3. Thus, there are 3 naturally occurring amino acids, so B can be HH, KK, RR, HHH, KKK, RRR, HK, HR, KH, KR, RH, RK, HHK, HHR, HKR, HKK, HRR, HRK, RHR, RHK and so on. The sequence  $[(X)_o(B)_nXBXXB]$  can be repeated 1 to 4 times. Thus, the possibilities of the amino acid sequence are vast and innumerable. Furthermore, since the claims have the open-ended language "having", this means that the amino acid sequence can be any lengths comprising the sequence  $(X_1)_p[(X)_o(B)_nXBXXB]_m(X_2)_q$ . Therefore, there is not sufficient amount of examples provided to encompass the numerous characteristics of the whole genus claimed.

14. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984)

(affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.



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functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

9. Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

10. The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative

**Rejection-35 U.S.C. 102**

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1-3 and 9-12 are rejected under 35 U.S.C. 102(e) as being anticipated by La Rosa et al (PG Pub 2004/0123343).

16. The instant claims are drawn to an amino acid sequence having the following formula  $(X_1)_p[(X)_o(B)_nXBXXB]_m(X_2)_q$  wherein X1 and X2 are amino acid sequences of 1 to 20 amino acids, p and q are whole numbers between 0 and 5, B is a basic amino acid, X is a non-basic amino acid, n is 2 or 3, m is 1 to 4 and o is 0 or 1.

17. La Rosa et al teach an amino acid sequence, SEQ ID NO: 178781 (enclosed) comprising the sequence --GKKKEKEMKEKKDKSDK--. The broad claim 1 recites "having" which is an open-ended language, meaning "comprising". The prior art teaches a 275 amino acid sequence that comprises the formula  $(X_1)_p[(X)_o(B)_nXBXXB]_m(X_2)_q$ . Thus, this meets the limitation of claims 1-3. Furthermore, since the amino acid sequence having the formula is presented in the prior art, this amino acid sequence would inherently have functionalities and properties of the amino acid sequence. Claims 9-12 do not further limit the amino acid sequence, but rather, claims characteristics of the amino acid sequence that it is "capable of reacting". This again, is an inherent

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property of the amino acid sequence. Thus, the prior art meets the limitations of the function claimed in claims 1 and 9-12.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

18. Claims 1-3 and 9-12 are rejected under 35 U.S.C. 102(a) as being anticipated by La Rosa et al (PG Pub 2004/0123343).

19. The instant claims are drawn to an amino acid sequence having the following formula  $(X_1)_p[(X)_o(B)_nXBXXB]_m(X_2)_q$  wherein  $X_1$  and  $X_2$  are amino acid sequences of 1 to 20 amino acids,  $p$  and  $q$  are whole numbers between 0 and 5,  $B$  is a basic amino acid,  $X$  is a non-basic amino acid,  $n$  is 2 or 3,  $m$  is 1 to 4 and  $o$  is 0 or 1.

20. La Rosa et al teach an amino acid sequence, SEQ ID NO: 178781 (enclosed) comprising the sequence --GKKKEKEMKEKKDKSDK--. The broad claim 1 recites "having" which is an open-ended language, meaning "comprising". The prior art teaches a 275 amino acid sequence that comprises the formula  $(X_1)_p[(X)_o(B)_nXBXXB]_m(X_2)_q$ . Thus, this meets the limitation of claims 1-3. Furthermore, since the amino acid sequence having the formula is presented in the prior art, this amino acid sequence would inherently have functionalities and properties of the amino acid sequence. Claims 9-12 do not further limit the amino acid sequence, but rather, claims characteristics of the amino acid sequence that it is "capable of reacting". This again, is an inherent property of the amino acid sequence. Thus, the prior art meets the limitations of the function claimed in claims 1 and 9-12.

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**Conclusion**


21. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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